MAY 2 4 2012

K120559

510(k) SUMMARY (as required by 21 CFR 807.92)

Miethke proSA Adjustable Shunt System
May 23, 2012

COMPANY: Aesculap®, Inc.
3773 Corporate Parkway
Center Valley, PA 18034
Establishment Registration Number: 2916714

CONTACT: Kathy A. Racosky
610-984-9291 (phone)
610-791-6882 (fax)
kathy.racosky@aesculap.com

TRADE NAME: Aesculap Meithke proSA Adjustable Shunt System

COMMON NAME: Hydrocephalus Shunt System

CLASSIFICATION NAME: Shunt, Central Nervous System and Components

REGULATION NUMBER: 882.5550

PRODUCT CODE: JXG

SUBSTANTIAL EQUIVALENCE

Aesculap, Inc. believes that the Aesculap Miethke proSA Adjustable Shunt System is substantially to Miethke proGAV Programmable Shunt System (K062009 / K103003) and Aesculap Miethke Shunt System (K011030 / K110206).

DEVICE DESCRIPTION

proSA is an adjustable gravitational valve that can be set for a range of pressures. The proSA valve is comprised of a titanium housing that contains a tantalum weight, leaf spring and ball mechanism that is mechanically controlled by internal magnets. Several manual devices are available to verify the pressure setting and to set or re-set the pressure pre and postoperatively. These manual accessories are for external use by the physician. Once verified using the verification instrument the setting must be confirmed with an X-ray. The device will be distributed by itself or in combination with the miniNAV valve or proGAV valve. The proSA adjustable gravitational valve includes the same legally marketed accessories that are available with the Miethke Shunt Systems.

INDICATIONS FOR USE

The Miethke proSA Adjustable Shunt System is intended to shunt cerebrospinal fluid (CSF) from the lateral ventricles of the brain into the peritoneum. Adjustments of the proSA shunt can be verified by using the verification instrument but must be confirmed by radiograph (X-ray).

TECHNOLOGICAL CHARACTERISTICS(compared to Predicate(s))

The Aesculap Miethke proSA Adjustable Shunt System is substantially equivalent to the predicate Aesculap Meithke Shunt System and Meithke proGAV Programmable Shunt System. The subject device is shown to be substantially equivalent and has the same performance characteristic to its predicate devices through comparison in design, principles of operation, intended use, and materials. The ShuntAssistant, proGAV and proSA device characteristics are summarized below.

	New Device Miethke Shunt System proSA Valve	Predicate Miethke Shunt System proGAV Valve K103003/K062009	Predicte Miethke Shunt System (ShuntAssistant) K103003/K011030
Adjustable	Yes	Yes	No
Valve Type	Adjustable Gravitational	Adjustable differential pressure	Gravitational
Materials			
Titanium Alloy Ti4Al6V	Yes	Yes	Yes
Neodym Ferrite Boron	Yes	Yes	No
Alpha Sapphire	Yes	Yes	Yes
Tantalum	Yes	No	Yes
Design	Circular	Circular	Cylindrical tube
Magnet	Yes	Yes	No
Pressure levels	Adjustable 0 - 40 cmH_2O	Adjustable 0 - 20 cmH_2O	Six pressure ranges 10 cmH_2O 15 cmH_2O 20 cmH_2O 25 cmH_2O 30 cmH_2O 35 cmH_2O
Manual Instruments	Yes	Yes	No
Tool settings and readings	0-40 cmH_2O	0-20 cmH_2O	N/A

PERFORMANCE DATA

Preclinical testing was performed to demonstrate that the Aesculap Miethke proSA Adjustable Shunt System performs as intended and is safe and effective. Testing was conducted in accordance with ISO 7197:2006 and included Leak, Pressure-Flow, Overpressure, Dynamic Break Strength, Bursting Pressure, Reflux performance, and Long Term Stability. Angle dependence testing was also performed.

In addition testing was performed according to the following MRI standards:

- ASTM F2119 Evaluation of MR Image Artifacts
- ASTM F2182 Measurement of Radio Frequency Induced Heating During Magnetic Resonance Imaging
- ASTM F2213 Qualitative Measurement of Magnetically Induced Torque in the Magnetic Resonance Environment
- ASTM F2052 Measurement of Magnetically Induced Displacement Force on the in the Magnetic Resonance Environment

The results and evaluation conclude that the device is MR Conditional in 3-Tesla Magnetic Resonance Imaging (MRI) systems according to ASTM F 2503 and is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Aesculap, Inc.
c/o Ms. Kathy Racosky
Senior Regulatory Affairs Specialist
3773 Corporate Parkway
Center Valley, PA 18034

MAY 2 4 2012

Re: K120559
Trade/Device Name: Miethke Adjustable proSA Shunt System
Regulation Number: 21 CFR 882.5550
Regulation Name: Central nervous system shunt and components
Regulatory Class: Class II
Product Code: JXG
Dated: February 23, 2012
Received: February 24, 2012

Dear Ms. Racosky:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

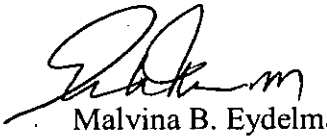
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K120559

Indications for Use

510(k) Number (if known): K120559

Device Name: Meithke proSA Adjustable Shunt System

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Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

JOE HUTTER

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K120559